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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/993,322 | 11/06/2001 | Derry Roopenian | JL-2010 | 5668 |

7590 [illegible]

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EXAMINER

LE, QUAN

| ART UNIT | PAPER NUMBER |
|---|---|
| [illegible] | 5 |

DATE MAILED: [illegible]

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 09/993,322 | ROOPENIAN, DERRY | |
| | Examiner | Art Unit | |
| | Q. Janice Li | 1632 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE ____ MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-80* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-80* are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S. C. 121:

I. Claims 1-6 are directed to a transgenic knockout mouse whose genome comprises a homozygous disruption in the endogenous FcRn gene, and a method of producing a monoclonal antibody using a FcRn-/- knockout mouse. Classified in Class 800, subclass 4 and 13.

II. Claims 7-13 are directed to monoclonal antibodies that specifically bind FcRn and a method for detecting FcRn molecules using a FcRn antibody. Classified in class 435, subclass 7.1, class 530, subclass 387.1.

III. Claims 14-21, 43, and 44 are drawn to a transgenic mouse whose genome comprises a homozygous disruption in the endogenous FcRn gene and also comprises a complete huFcRn gene or a huFcRn cDNA construct for expressing a functional human FcRn protein, and a method to identify a therapeutic agent using the transgenic mouse. Classified in Class 800, subclass 3 and 13.

IV. Claims 22 and 45 are drawn to a transgenic mouse whose genome comprises a homozygous disruption in the endogenous FcRn gene and IgG gene; and also comprises a DNA construct for expressing a functional human FcRn and IgG protein, and a method to identify a therapeutic agent using the transgenic mouse. Classified in Class 800, subclass 3 and 13.

V. Claims 23 and 46 are drawn to a transgenic mouse whose genome comprises a homozygous disruption in the endogenous FcRn gene; and also comprises a DNA construct for expressing a functional human FcRn and IgG protein, and a method to identify a therapeutic agent using the transgenic mouse. Classified in Class 800, subclass 3 and 13.

VI. Claims 24 and 25 are drawn to a method to identify an inhibitor of FcRn mediated protection of IgG antibodies using functional huFcRn/hubeta-2M complexes in liquid or bound to solid support. Classified in Class 204, subclass 450.

VII. Claims 26-29 and 65-80 are drawn to a method to identify an inhibitor of FcRn mediated protection of IgG antibodies or o identify a candidate formulation for FcRn-mediated drug stabilization using cultured mammalian cells expressing huFcRn and a trackable composition. Classified in Class 435, subclass 69.2.

VIII. Claims 30 and 47-64 are drawn to a method to identify an inhibitor of FcRn mediated protection of IgG antibodies or to identify a candidate agent for FcRn-mediated drug delivery in an individual using an FcRn-/-, and huFcRn+ knockout-transgenic mouse. Classified in Class 800, subclass 3.

IX. Claims 31-38 are drawn to a method to inhibit FcRn mediated IgG protection in an individual comprising administering a monoclonal antibody or an engineered molecule that specifically binds huFcRn and inhibits binding of huFcRn to IgG. Classified in Class 514, subclass 2.

X. Claim 39 is drawn to a method to inhibit FcRn mediated IgG protection in an individual comprising administering an organic molecule which binds FcRn and inhibits binding

of huFcRn to IgG. Classification is to be determined depending on the type of organic molecule used.

XI. Claims 40-42 are drawn to a method to inhibit FcRn mediated IgG protection in an individual comprising administering an inhibitor of FcRn expression to the individual, wherein the inhibitor inhibits expression of FcRn at the transcription, translation, post-translational processing or protein transport to the membrane. Classification is to be determined depending on the type of inhibitors used.

2. The inventions are distinct, each from the other because of the following reasons.

Inventions II-V and I are independent and distinct inventions. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, each of the groups I-V is drawn to a different product and a method of using such, i.e. different transgenic animals and antibodies. The different products are distinct in chemical structure and biological function. For example, each type of knockout or transgenic-knockout mouse have different genetic manipulation in their genome, thus, would present a distinct phenotype.

Inventions VII-XI, and VI are independent and distinct inventions. Inventions are distinct if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, groups VI-VIII are drawn to different methods of screening for desired agents. The different methods use different materials for screening, the

transgenic/knockout mice of group VIII would not be used in any of the groups VI and VII. The different methods use different starting materials, different criteria for testing, have different method steps and require distinct technical considerations. Groups IX-XI are drawn to different therapeutic methods comprising administering different reagents influencing FcRn mediated IgG protection in an individual. The different agents have distinct chemical structures and mode of operation. For example, group XI requires the reagents that influence expression of FcRn at the transcription or post-translational processing, which is not required in either groups IX or X, the antibodies of group IX is not used in group X. Accordingly, the different methods require distinct technical considerations and search criteria.

The differences of the Inventions I-XI are further underscored by their divergent classification and independent search criteria.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different search criteria, it would impose an undue burden to the Office if all the groups are examined together, thus, restriction for examination purposes as indicated is proper.

3. This application contains claims directed to the following patentably distinct species of the claimed invention: Invention groups I, III-V embrace transgenic knockout mice characterized as having different background genotype, if one of the groups I, III-V are elected, further election of a species with a particular background genotype is necessary. Invention group VII comprises species of trackable composition; invention group VIII comprises species of trackable composition and different types of animals, i.e. adult, fetus, or neonate. If one of the groups VII or VIII is elected, further election of a species is necessary. Invention groups X and XI are drawn

to using different organic molecule and agents that inhibits FcRn expression. If one of the groups X or XI is elected, further election of a species for examination is necessary. It is noted that the groups X and XI may encompass genuses of molecules that would perform the required function, in that case, the election may be drawn to a distinct invention rather than a species.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-6, 14-23, and 26-80 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is advised that where a single claim encompasses more than one invention as defined above, upon election of an invention for examination, said claim will only be examined to the extent that it reads upon the elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).

Q. Janice Li
Examiner
Art Unit 1632

QJL
January 9, 2003

ANNE M. WEHBE PH.D.
PRIMARY EXAMINER